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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,740	06/23/2000	Markus Pompejus	BGI-126CP	1632

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EXAMINER	
KERR, KATHLEEN M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,740	POMPEJUS ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,9-14,17,25-29 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,4,10-12,25-29 and 31-33* is/are allowed.

6)☒ Claim(s) *5,6,9,13,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: *alignment*.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a Final rejection (mailed on January 14, 2003), Applicants filed an after-final amendment received on February 17, 2004. Said amendment has been entered and cancelled Claims 7, 8, 15, 16, 34, 36, and 37 and amended Claims 9 and 29. Thus, Claims 1, 4-6, 9-14, 17, 25-29, and 31-33 are pending in the instant Office action and will be examined herein.

The **FINALTIY** of the previous Office action, mailed on January 14, 2003, **is** herein **WITHDRAWN**; prosecution is being reopened to address issues concerning the pending claims.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/141,031, filed on June 25, 1999, 60/143,208, filed on July 9, 1999, and 60/151,572, filed on August 31, 1999.

The Examiner herein notes an inability to identify support for SEQ ID NOs:1/2 in said provisional applications. Thus, the instant claims are granted the benefit of priority to June 23, 2000, the filing date of the instant application. If the Examiner is in error, Applicants must cite clear support (page of the provisional application) where SEQ ID NOs:1/2 can be found.

3. As previously noted, without certified translations of the foreign applications whose foreign priority has been requested (27 German applications), priority cannot be granted. Applicants have noted that certified copies would be filed upon issuance of a patent. Thus,

foreign priority is herein **NOT** granted. Acknowledgment is made of applicant's claim for foreign priority based on applications (27 total) filed in Germany.

Withdrawn - Objections to the Specification

4. Previous objection to the specification for being confusing in its description of SEQ ID NOs: 1/2 as described in Table 1 is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Objections

5. Previous objection to Claim 15 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicant's cancellation of said claim.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

6. Previous rejection of Claim 29 under 35 U.S.C. § 112, second paragraph, as being indefinite for particular genus/species names is withdrawn by virtue of Applicants' amendment.

7. Previous rejection of Claims 36 and 37 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicants' cancellation of said claims.

8. Previous rejection of Claims 7-9 and 34 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's cancellation of said claims.

9. Previous rejection of Claims 7-9 and 34 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's cancellation of said claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

10. Previous rejection of Claims 7-9 under 35 U.S.C. § 102(b) as being anticipated by Marra *et al.* is withdrawn by virtue of Applicant's cancellation of said claims.

NEW ISSUES

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 5 and 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 5, the phrase "naturally occurring" is unclear as to its metes and bounds. For example, allelic variants are considered to be within the metes and bounds of the claims while genetically engineered point mutations would not. Since the metes and bounds of *all* naturally occurring allelic variants are unknown, what is made via genetic engineering today (outside the scope of the claim) may be found as a naturally occurring allelic variant tomorrow (inside the scope of the claim). Thus, the metes and bounds are ill defined. Clarification is required. The Examiner suggests removal of the term "naturally occurring" for clarity.

12. Claims 13-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Since Claim 12 is drawn to transfected host cells, it is unclear how microorganisms, which are transformed, not transfected, appropriately further limit the subject matter of the parent claim. Clarification is required. The Examiner suggests amending Claim 12 to ---transformed---.

13. Claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Since host cells make numerous polypeptides, it is unclear is the "produced" polypeptide in the claim is that which is encoded by the expression vector. This is implied, but not clear from the claim language. Clarification is required. The Examiner suggests amending to a method of producing SEQ ID NO:2.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 5 and 9 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Although the genus of allelic variants that are the result of the translation of single nucleotide polymorphisms is discussed in the specification, there is no evidence that any representative species of the genus was in the

possession of the inventors at the time of filing. Moreover, the specification, as filed, has not described this sub-genus of polypeptides that are within the hybridization conditions of Claim 5.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

The specification does not disclose any representative species of allelic variants, with or without identifying characteristics. Moreover, the specification does not adequately describe the subgenus of polypeptides that are variants of SEQ ID NO:2 as the result of the translation of SNPs because none are described, either expressly or predictably. Thus, one of skill in the art would be unable to identify members of the claimed genus of Claims 5 and 9. Therefore, Claims 5 and 9, as written, fail to satisfy the written description requirement. To obviate the instant rejection, the Examiner suggests removing "allelic variant" from the claims.

15. Claims 5, 6, and 9 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides that encode SEQ ID NO:2, does not reasonably provide enablement for polynucleotides with such low sequence identity, such as the 90% identity claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The amount of experimentation required of one of skill in the art to use the claimed invention to the full extent of its scope is undue.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

Applicants present no guidance or working examples of the use of polynucleotides that have such low sequence identity with respect to SEQ ID NO:1. The nature of the invention is such that the DNA encodes a functional protein, a 6-phosphogluconolactonase that functions in the pentose phosphate pathway; and with such a great deviation from the known sequence, the predictability of functionality becomes extremely low. Such breadth and unpredictability renders the instant claims not enabled to the full extent of their scope without undue experimentation. Moreover, the art includes few examples of genes encoding 6-phosphogluconolactonases. The

art fully enables any DNA encoding SEQ ID NO:2 based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other 6-phosphogluconolactonase genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find a 6-phosphogluconolactonase gene, which is structurally related to SEQ ID NO:1, is not equivalent to the ability to make a 6-phosphogluconolactonase gene as required by the statute (i.e., "make and use"). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its 6-phosphogluconolactonase-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

Examiner's Comments

16. The following are noted as related art:

a) **USPAP 2002/0197605** (Nakagawa *et al.*) is cited herein as related art that teaches a DNA exactly encoding SEQ ID NO:2; previously, EP 1108790 with a related disclosure had been cited. This USPAP is not prior art under 35 U.S.C. § 102(e) in the instant application because the filing date is December 18, 2000, which does not pre-date the filing date of the instant application of June 23, 2000.

b) **WO 01/004322** (Dunican *et al.*, previously cited by the Examiner non April 22, 2002) teaches a polynucleotide identical to SEQ ID NO:1 but is not available as prior art by means of its filing date (not being before November 29, 2000) or its publication date.

c) **WO 01/004325** (Dunican *et al.*) teaches a polynucleotide identical to SEQ ID NO:1 (see attached alignment) but is not available as prior art by means of its filing date (not being before November 29, 2000) or its publication date. The Examiner notes that this international application claims priority to a U.S. application whose filing date pre-dates the filing date of the instant application, which is the earliest effective filing date granted in this case. The Examiner recommends perfection of any priority claims related to the pending claims.

17. The nucleic acid of SEQ ID NO:1 is disclosed as encoding a 6-phosphogluconolactonase whose expression is useful in the production of amino acids in *Corynebacterium*; thus, a specific and credible utility has been asserted for the pending claims.

Summary of Pending Issues

18. The following is a summary of the issues pending in the instant application:

a) Claims 5 and 9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "naturally occurring".
b) Claims 13-14 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for being transfected, not transformed, microorganisms.
c) Claim 17 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the production of which polypeptides.
d) Claims 5 and 9 stand rejected under 35 U.S.C. § 112, first paragraph, written description (allelic variants).
e) Claims 5, 6, and 9 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

Conclusion

19. Claims 1, 4, 10-12, 25-29, and 31-33 are allowed. Claims 5, 6, 9, 13, 14, and 17 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **NON-FINAL**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kathleen M Kerr
Examiner
Art Unit 1652

March 29, 2004